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before the
Taskforce on Drug Importation
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Thank you for the opportunity to address the Taskforce on the controversial issue of drug importation. From Public Citizen's perspective, drug importation will never be more than a band-aid solution to the underlying problem: out-of-control drug prices. As is well known, drug prices in foreign countries are often half of what they are for identical drugs in the United States. The reason for this is simple: unlike every other industrialized country, the United States refuses to negotiate drug prices or, as is done in Britain, negotiate a guaranteed profit margin for pharmaceuticals. In fact, we are in many respects going in the opposite direction; the recently passed Medicare prescription drug legislation actually prevents the Medicare program from using its massive purchasing power to negotiate lower drug prices.

These spiraling drug prices have driven consumers to look to foreign countries, particularly Canada, to obtain prescription drugs at affordable prices. Were it not for this importation, we would likely not be seeing the degree of concern currently being professed at the Food and Drug Administration (FDA), in particular, over the problem of counterfeit medications. Counterfeits are a long-standing problem in U.S. health care, predating the importation debate by decades. The problem is not restricted to imports; domestically manufactured drugs are also all-too-frequently counterfeited or adulterated.

Yet, while the FDA continues to raise concern over counterfeiting, in part by producing misleading reports that exaggerate the problem or focus on the importation dimension of it alone, the agency is in fact part of the problem. A law that was designed to cut down on counterfeiting has, 17 years after it was passed, still not been implemented, thanks to industry-inspired delays at the FDA.

The current situation can be appreciated by analogy. If a car develops a safety problem, the manufacturer has the ability to track down each car from, for example, that model-year to inform the current owner of the problem, no matter how many times the car has been resold. Incredibly, this is not possible for pharmaceuticals. A document could easily circulate with the batch of drugs with each resale, greatly reducing the possibility for counterfeiting or adulteration, because the perpetrator could be more easily identified. Such a document, called a pedigree, was mandated by Congress in the Prescription Drug Marketing Act (PDMA) of 1987. Even the pharmaceutical companies support it, presumably because it would protect their brands from being tarred by counterfeit knock-offs. In 1988, the FDA issued a guidance document that laid out its interpretation of the PDMA. However, the FDA did not even propose a regulation to implement the PDMA until 1994 and a final regulation was not completed until 1999. In fact, the final regulation was very similar to the 1988 guidance. It was only at that point that

complaints from the drug wholesaling industry began in earnest. Ironically, it is among these very wholesalers that the counterfeiters lurk. Nonetheless, the FDA has "delayed" implementation of the rule five times; through these accumulating stalling tactics, the FDA has so far succeeded in frustrating the intent of Congress for 17 years.

Historically, the path from a pharmaceutical manufacturer to a consumer was relatively simple: manufacturers sold to wholesalers who sold to hospitals or pharmacists who administered medications or filled prescriptions. Over the years, this path has become circuitous. Secondary wholesalers might obtain the drugs from one of the three major (primary) wholesalers and then sell it to hospitals or pharmacists. Sometimes primary wholesalers obtain drugs from the secondary wholesalers. Occasionally, secondary wholesalers may procure the drugs from the manufacturer themselves. These circuitous roots to the patient, combined with the lack of a pedigree, provide the opportunity for counterfeiters and other fly-by-night operators to insert themselves into the process. In the process, quality assurances may be lost as drugs are not properly stored, for example.

This is where it starts to get a bit technical. At the time the PDMA was enacted, Eli Lilly had contracts with more than a dozen wholesalers, which were the sole companies through which Lilly sold its products. To accommodate Lilly, Congress considered these wholesalers to be "authorized" and limited the PDMA's pedigree requirement to "unauthorized" wholesalers. Congress defined authorized wholesalers as those "with whom a manufacturer has established an on-going relationship to distribute such manufacturer's products." But the FDA, in interpreting the PDMA in its never-implemented regulations, took a much broader view of what defined an "authorized" wholesaler: a wholesaler with at least two transactions with a particular pharmaceutical company in a 24-month period *and* a contract with that manufacturer. Obviously, this is not a very stringent definition, but even that was not good enough for the secondary wholesalers. They simply ignored the guidance and disregarded the requirement for the contract. Thus, any wholesaler with two transactions with a company over two years would be considered "authorized" and thus exempt from the pedigree requirement. In current practice, therefore, most wholesalers simply consider themselves to be authorized, effectively gutting the PDMA.

Congress also required that a pedigree be maintained on "each prior sale, purchase or trade," a requirement the FDA interpreted as applying to "all parties to each prior transaction ... starting with the manufacturer." This seems logical and consistent with Congress' intent. But the secondary wholesalers prefer to interpret the pedigree requirement in the guidance (and the final regulation) as reaching back in the distribution chain only as far as the last authorized wholesaler; thus each time a drug passes through the hands of an authorized wholesaler (using the least restrictive definition, of course), the slate (and the requirement for a pedigree) would be wiped clean.

This important public health issue has thus been in limbo since 1987, with the FDA never implementing its regulations but nonetheless assailing counterfeiters and importers who are aided and abetted by the FDA's failure to regulate. Meanwhile, the secondary

wholesalers practice business as usual – all at the cost of potentially exposing U.S. patients to counterfeit and adulterated drugs.

If the agency believes that the PDMA somehow needs revision, then it is incumbent upon it to approach the Congress and make that case. It is not acceptable to simply defy the Congress by writing overly permissive regulations and then never implement them. One final note: In its most recent Federal Register notice delaying the implementation of the 1999 regulations, the FDA further delayed any action until December 1, 2006.